pathologies. Of 30 AF positive lesions we were able to define the subgroup of 19 locations with specific spectroscopy pattern corresponding wit non-malignant histology. NBI bronchoscopy is not simple to interpret but gives promising results in discrimination between malignant and benign endobronchial tissue.

C4-05 **Chest Medicine, Wed, 10:30 - 12:15**

Comparison of Real-time endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) and PET/CT in mediastinal staging of NSCLC: focus on histologic types. (preliminary report)

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Background: EBUS-TBNA was reported to have higher diagnostic accuracy in lymph node (LN) staging of lung cancer compared to CT and PET. We conducted a prospective study to compare EBUS-TBNA with PET/CT in mediastinal LN staging, especially focused on histologic types of NSCLC.

Methods: EBUS-TBNA was performed in 73 potentially operable NSCLC patients (pts) (M/F 60/13, median age 64 yrs). Chest CT and PET/CT were done before EBUS-TBNA. In case mediastinal LN metastasis was not proved by EBUS-TBNA, surgery was performed.

Results: Out of 73 pts, 34 had adenocarcinoma (ADC) and 32 had squamous cell ca (SCC)(large cell ca n=4, non-small cell ca unspecified, n=3). One hundred twenty-six mediastinal LNs (2R = 6, 2L=1, 4R=44, 4L=26, 7N=49) were sampled by EBUS-TBNA in 73 pts. EBUS-TBNA demonstrated metastasis in 34 LN stations in 23pts and missed 1 N2(+) patient (station 7, SCC). Overall, EBUS-TBNA showed higher diagnostic accuracy than PET/CT in mediastinal LN staging (Table, p=0.0075). EBUS-TBNA demonstrated LN metastasis in 3 PET (-) patients. All 3 pts had ADC. In ADC, positive predictive value (PPV) and negative predictive value (NPV) of PET/CT were 81.3% and 83.3% respectively. In SCC, PPV of PET/CT was very low (33.3%) and NPV was high (94.1%).

Conclusion: EBUS-TBNA is useful in mediastinal LN staging especially for the pts with mediastinal PET (-) adenocarcinoma and PET (+) NSCLC.

		Sensitivity	Specificity	PPV	NPV	Accuracy
Total, n=73	PET/CT	83.3(20/24)	69.3(34/49)	57.1(20/35)	89.5(34/38)	74.0(54/73)
	EBUS-TBNA	95.8(23/24)	100(49/49)	100(23/23)	98.0(49/50)	98.6(72/73)
ADC, n=34	PET/CT	81.3(13/16)	83.3(15/18)	81.3(13/16)	83.3(15/18)	82.4(28/34)
	EBUS-TBNA	100(16/16)	100(18/18)	100(16/16)	100(18/18)	100(34/34)
SCC, n=32	PET/CT	83.3(5/6)	61.5(16/26)	33.3(5/15)	94.1(16/17)	65.6(21/32)
	EBUS-TBNA	83.3(5/6)	100(26/26)	100(5/5)	96.3(26/27)	96.9(31/32)

C4-06 **Chest Medicine, Wed, 10:30 - 12:15**

Photodynamic therapy using talaporfin sodium (NPe6) for centrally located early stage lung cancer

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Backgroud: We had previously developed the possibility of use of a photodynamic diagnosis (PDD) system using a tumor-selective photosensitizer and laser irradiation for the early detection and photodynamic therapy (PDT) of centrally located early lung cancers. Recently, we established the autofluorescence diagnosis system integrated into a videoendoscope (SAFE-3000) as a very useful technique for the early diagnosis of lung cancer.

Patients and Methods: Thirty-four patients (45 lesions) with centrally located early lung cancer (Squamous cell carcinoma, carcinoma in situ, TisN0M0, stage 0) received PDT using the second-generation photosensitizer, talaporfin sodium (NPe6), and a diode laser (664 nm). Just before the PDT, we defined the tumor margin accurately using the novel PDD system SAFE-3000 with NPe6 and a diode laser (408 nm).

Results: Red fluorescence emitted from the tumor by excitation of the photosensitizer by the diode laser (408 nm) from SAFE-3000 allowed accurate determination of the tumor margin just before the PDT. The complete remission (CR) rate following NPe6-PDT in the cases with early lung cancer was 93.3% (42 /45 lesions). We also confirmed the loss of red fluoresce from the tumors immediately after the PDT using SAFE-3000. We confirmed that all the NPe6 in the tumor had been excited and photobleached by the laser irradiation (664 nm) and that no additional laser irradiation was needed for curative treatment.

Conclusions: This novel PDD system using SAFE-3000 and NPe6 improved the quality and efficacy of PDT and avoided misjudgment of the dose of the photosensitizer or laser irradiation in PDT.

C4-07 **Chest Medicine, Wed, 10:30 - 12:15**

evaluation of radiofrequency ablation for thoracic malignancies using PDG-PET-CT scan

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Background: Radiofrequency ablation therapy (RFA) is widely applied for the treatment thoracic malignancies as a modality of local control therapy lately. RFA procedure itself is thought to be almost safe. However, assessment of therapeutic efficacy following RFA procedure is not well established.

Lately, the use of FDG-PET-CT scan has been advocated for early tumor diagnosis or early recurrent cancer detection in the field of thoracic malignancies. Although several studies showing the benefit of FDG-PET-CT scan in RFA for thoracic malignancies have been reported, optimal timing of examinations after RFA, appropriate fol-

low-up schedule are still unknown. We are currently conducting Phase I/II study for RFA for thoracic malignancy using FDG-PET-CT as an evaluation procedure. Here we report the result of our study and usefulness of FDG-PET-CT scan as an evaluation procedure after RFA.

Method: In the last two years, we performed RFA on 11 patients who had thoracic malignancy. We evaluated 9 patients out of 11 who had positive FDG accumulation to tumors in this study. They were 8 males and 1 female with a mean age of 75.2 years (range of 65-81years old). Two patients had primary lung cancer, 4 patients had recurrent lung cancer, 3 patients had metastatic tumor. Tumor size were 0.8-2.5cm in diameters (mean: 1.64cm). All patients were not candidate to surgery because of their cardiac or pulmonary dysfunctions and underwent CT-guided percutaneous RFA under local anesthesia.

Result: No mortality and no major morbidity were noted. Morbidity was observed 5 cases out of 9 patients (55.6%) included 3 patients with pneumothorax without drainage, 1 patient who had chest pain during ablation and 1 patient who had fever without any treatment after RFA. Obvious decrease of FDG accumulation was observed in early examination (7-14days) after RFA in 8 patients out of 9, only 1 patient showed stable accumulation of FDG.

After ,S-16months (mean follow up period were 9.75M) follow up periods, those 8 patients had no clear local recurrence.

Conclusion: RFA for thoracic malignancy seems to be safe and feasible. Early examinations of FDG-PET-CT scan after RFA may be useful for evaluation of a local control. To clarify the effectiveness of RFA on patients' survival, it still is needed that larger series clinical trial and much longer observation.

Session C5: Mesothelioma

Wednesday, September 5

C5-01 **Mesothelioma, Wed, 10:30 - 12:15**

Open-label study of pemetrexed alone or in combination with a platinum in chemonaïve patients (pts) with malignant pleural mesothelioma (MPM): Results from the International Expanded Access Program (EAP)

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Background: An EAP was developed for the use of pemetrexed (P) in patients with MPM before and during review by regulatory agencies. Previous studies showed promising results for the use of single-agent P or the combination of P+platinum for chemonaive pts with MPM. The phase II study (Scagliotti 2003) of P showed a response rate (RR) of 14.1% (95% CI 6.6, 25.0), time to progressive disease (TtPD) of 4.7 mos (95% CI 4.2, 5.8), and median survival time of 10.7 mos (95% CI 7.7, 14.5), with a 1-yr survival rate of 47.8%. The phase III study of P+cisplatin (Cis) versus Cis in MPM demonstrated a significantly different RR (41.3% vs 16.7% p<0.001), TtPD (5.7 mos vs 3.9 mos, p=0.001), and survival benefit (median survival: 12.1 mos vs 9.3 mos, p=0.020; 1-yr survival: 50.3% vs 38.0%, p=0.012) in favor of P+Cis (Vogelzang 2003). The EAP provided access to P alone or P plus Cis or carboplatin (Cb) for 3312 pts in 13 countries. Safety and efficacy data for chemonaïve pts receiving P or P+platinum are summarized in this abstract.

Methods: Eligible pts had histologic or cytologic diagnosis of MPM not amenable to curative surgery. P 500 mg/m^2 alone or in combination with either Cis 75 mg/m^2 or Cb AUC 5 was given on day 1 of each 21-day cycle, with standard premedication consisting of vitamin B12, folic acid, and dexamethasone. Investigator-determined best response (RR) and survival data (with censoring) were recorded at the end of study participation. Myelosuppression data (NCI CTC, version 2.0) were also collected.

Results: In this nonrandomized, open-label study 2023 chemonaïve pts received ≥ 1 dose of P (319 pts), P+Cis (843 pts) or P+Cb (861 pts) and were evaluable for safety. Of the study participants, 247 P pts, 745 P+Cis pts, and 752 P+Cb pts were evaluable for efficacy. Baseline characteristics, and efficacy and safety data are summarized in the table.

Conclusions: In this large, nonrandomized study, all three treatment arms (P, P+Cis, and P+Cb) had clinically similar one-year survival rates, whereas the combination arms had higher response rates than P alone. These results confirm the efficacy of P or P+platinum in the treatment of chemonaive pts with MPM.

	P	P+Cis	P+Cb
Median age (years) (range)	69 (39-87)	62 (24-78)	66 (35-89)
Male (%)	78.1	85.3	80.5
Karnofsky performance status ≥ 80, % of pts*	71.6	86.8	85.8
RR, % of pts (95% CI)	10.5 (7. 0, 15.0)	26.3 (23.2, 29.6)	21.7 (18.8, 24.8)
Disease control rate (responders +SD), % of pts (95% CI)	59.1 (52.7, 65.3)	77.7 (74.6, 80.7)	75.8 (72.6, 78.8)
One-year survival rate, % (95% CI)	58.6 (43.4, 73.8)	63.1 (50.7, 75.5)	64.0 (53.3, 74.6)
Median TtPD (months) (95% CI)	6.0 (4.6, 7.2)	7.0 (6.7, 8.3)	6.9 (6.6, 7.7)
Leukopenia, Gr 3/4, % of pts	14.7	13.1	21.0
Neutropenia, Gr 3/4, % of pts	17.3	23.9	36.1
Thrombocytopenia, Gr 3/4, % of pts	2.9	5.0	14.3
Anemia, Gr 3/4, % of pts	7.5	7.2	14.3

* >90% of pts in each treatment arm were assessed for performance status.